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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,043	12/21/2001	Wilson Burgess	CI-0013	7597

34610 7590 05/20/2003

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/024,043

Applicant(s)  
Burgess et al.

Examiner  
Vera Afremova

Art Unit  
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 26, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 4, 54-63, 76-78, 89, 92-101, 103, and 104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 2, 3, 5-53, 64-75, 79-88, 90, 91, and 102 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |                                                                |                                                    |
|----------------------------------------------------------------|----------------------------------------------------|
| 1) Notice of References Cited (PTO-892)                        | 4) Interview Summary (PTO-413; Paper No(s))        |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)    | 5) Notice of Informal Patent Application (PTO-152) |
| 3) Information Disclosure Statement(s) (PTO-1449; Paper No(s)) | 6) Other                                           |

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### **DETAILED ACTION**

Applicants' election with traverse of the Group II (claims 2 and 3 and claims 5-53, 64-75, 79-88, 90, 91 and 102 as depending on claims 2 and/or 3) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the Group II (claims 2 and 3 ) and the Group III (claim 4) are classified in the same class and, thus, they should be examined together. This is not found persuasive because classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists.

The elected claims of the Group II (2, 3, 5-53, 64-75, 79-88, 90, 91 and 102) are subject to the election of species requirement.

#### ***Election***

This application contains claims directed to the following patentably distinct species of the claimed invention drawn to different stabilizing processes and this application contains claims directed to the following patentably distinct species of the claimed invention drawn to different types of radiation which are used to sterilize heart valves sensitive to radiation.

1. The species as drawn to the different stabilizing processes are the processes (a) through (f) as indicated in claims 2 or 3, for example: stabilizing process (a) by adding one stabilizer to protect heart valves from radiation (claims 29-38); stabilizing process (b) by reducing the residual solvent content to protect heart valves from radiation (claims 5, 19-26, 66-75, 79, 80, 90,

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91, 102); stabilizing process (c) by reducing temperature to protect heart valves from radiation (claims 49-53 and 81); stabilizing process (d) by reducing oxygen content to protect heart valves from radiation (claims 15-18); stabilizing process (e) by adjusting pH to protect heart valves from radiation (claims 2 and 3); stabilizing process (f) by adding one non-aqueous solvent to protect heart valves from radiation (claims 64 and 65).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species drawn to a stabilizing process for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2, 3, 27, 28 and 82-88 are generic.

Please, note that the phrases "the residual solvent" (claim 2, line 7; claim 3, line 6) lack antecedent basis.

2. The species as drawn to the different types of radiation are electromagnetic radiations and corpuscular radiations, for example: gamma radiation (claim 41), E-beam radiation (claim 42), visible light radiation (claim 43), ultraviolet (claims 44), x-ray radiation (claim 45), polychromatic visible light (claim 46), infrared radiation (claim 47), combination of visible and ultraviolet light (claim 48), .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species drawn to one type of radiation for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2 and 3 are generic. Claims 39 and 40 will be examined as drawn to the elected type of radiation of the claims 41, 42, 43, 44, 45, 46, 47

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or 48. With respect to the claims 6-14, which might be considered generic, it is uncertain whether they are intended for gamma radiation or for the other claimed type of radiation. Please, indicate for what types of radiation the claimed amounts are intended.

Applicant is advised that a reply to this requirement must include an identification of the species (stabilizing process and radiation type) that are elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Vera Afremova

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May 12, 2003.

VERA AFREMOVA

PATENT EXAMINER

  
MICHAEL WITYSHYN  
Supervisory Patent Examiner  
Technology Center 1600